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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,507	05/06/2002	Dirk Wernicke	3658-0103P	5925

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EXAMINER

GUO, LYNDIA T

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/31/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/979,507

Applicant(s)

WERNICKE ET AL.

Examiner

Lynda T Guo

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

Applicant's Response to the notice of missing requirements (PCT/DO/EO/905) was received on 08 May 2002 and entered as Paper No. 7.

Claims 1-12 of the present Application are pending.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

Art Unit: 1651

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

1. The disclosure is objected to because of the following informalities:

The present Specification is not in proper format. For example, the "Brief Description of Drawings" is not in the present Specification and the different sections are not properly labeled. See the above guidelines for the preferred layout of a specification.

Appropriate correction is required.

Drawings

2. The drawings are objected to because translation of the words in the figures is incomplete (see Figure 1, "interstitielle" and Figure 2 "Cortikosteroid). Additionally, there are typos in the figures (e.g. Figures 1 and 3, "synovialmembrane" and Figure 2, "Therapie"). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 does not recite any steps for the detection of collagenase 3. Standard method steps include contacting, determining and correlating. Claim 1 lacks all three.
6. The following do not have sufficient antecedent basis:
 - Claim 2, "the progression of rheumatoid arthritis",
 - Claim 3, "the collagenase 3 mRNA expression",
 - Claim 4, "the collagenase 3 antigen",
 - Claim 5, "the catalytic activity" and "the activated collagenase 3",
 - Claim 6, "the quantitative relationships",
 - Claim 10, "the detection of an increased genetic predisposition", AND
 - Claim 11, "the increase of the clinical relevance" and "the detection of an increased genetic predisposition".
7. Regarding claim 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
8. Claims 11 and 12 are generally narrative and indefinite, failing to conform with current U.S. practice. The Claims appear to be a literal translation into English from a foreign document and is replete with grammatical and idiomatic errors. For example, it is unclear what is meant by "the increase of the clinical relevance of the meaningfulness" in Claim 11. Consequently, Claim 11 cannot be search, as written.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al. (Publication number JP 08226918A, now patent number JP 2864219).

NOTE: This present rejection under 35 U.S.C. 102(b) is based upon the **abstract only** of the above cited document, published on 03 September 1996. The publication is believed to be the equivalent of the patent. A full translation of the publication into the English language will be supplied in the next Office Action.

Claims 1, 2, 7, 9 and 12 are drawn to a method of detecting destructive joint diseases by detecting collagenase 3 (i.e. MMP-13) and optionally in conjunction with detecting MT1-MMP (i.e. MMP-14) and/or gelatinase A (i.e. MMP-2).

Fujimoto et al. disclose a method in which MMP 1-3 and 7-13 are detected in tissues or humor by use of monoclonal antibodies and the method is useful in the diagnosis of chronic rheumatism and deformed arthritis. Therefore, the limitations set forth in the recited claimed are fully encompassed by Noboru's disclosure and the Claims are consequently rejected.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,143,506 (Golub et al.) in view of Wernicke et al. (1996).

The present Application is drawn methods of detecting destructive joint diseases (e.g. rheumatoid arthritis) comprising detecting collagenase 3 as the marker in tissues and body fluids. Claimed methods include mRNA or protein expression, immuno-detection, measuring catalytic activity and inhibition assays.

In USPN 6,143,506, Golub discloses methods for the detection of periodontitis or peri-implantitis by detecting matrix metalloproteinase-13 (i.e. MMP-13 or collagenase 3). (See Column 30, Claim 1). Golub teaches that periodontal disease is a group of inflammatory disorders that affect gingival, periodontal **ligament** and alveolar **bone** structures supporting the teeth. Though Golub does not teach that the method is useful for diagnosing destructive joint diseases, Golub does disclose that MMP-13 plays an important role in the destruction of connective tissues during arthritis (inflammation of the joints), (Column 12, lines 27-32). Other literature also teaches that MMP-13 is highly expressed in the synovial membrane of patients with rheumatoid arthritis and osteoarthritis (Wernicke, page 590, column 2, paragraph 2). Since MMP-13 is a known marker for diagnosing periodontal disease (a group of inflammatory disease affecting ligaments, bones and soft tissues) and Wernicke teaches that MMP-13 is

Art Unit: 1651

present in tissues affected with a destructive joint disorder (i.e. inflammatory diseases of the joints), there is a reasonable expectation of success that MMP-13 will also be useful as a marker for diagnosing destructive joint disorders due to the similar nature of the two groups of diseases and the fact that the same marker (i.e. MMP-13) is present in both disease groups. Therefore, it would have been obvious, at the time the invention was made, to one of ordinary skill in the art to use the diagnostic method, as disclosed by Golub, for the diagnosis of destructive joint diseases.

In regards to the different methods as recited in Claims 3-6, 10 and 12, these are all methods that are well known in the art, as evidenced by USPN 6,143,506, Lindy et al. (1997) and Stahle-Backdahl et al (1997). The methods disclosed USPN 6,143,506 include measuring the catalytic activity of the pro-enzyme as well as the activated enzyme (Column 4, lines 26-36, Column 9, lines 30-34 and Column 16, lines 29-35). Lindy et al. disclose methods used in measuring mRNA expression, protein expression, inhibition comparisons and localization determination, for example, via immunohistochemical staining (Abstract, second and last paragraphs, page 1392, right column, page 1393, right column, page 1394, right paragraph and page 1398, left column, second paragraph). Stahle-Backdahl et al. disclose a method in which MMP-13 is detected along with gelatinase A and MT1-MMP (Page 726, right column, "In situ Hybridization" section).

In regards to the samples in which the claimed methods are performed on (Claims 7-9), all the above-cited references disclose various tissues and/or fluids in which MMP-13 is present. For example, Stahle-Backdahl et al. obtained samples of cartilage tissue from patients sero-positive for rheumatoid arthritis that underwent orthopedic surgery and synovial fluids from the knees of

Art Unit: 1651

rheumatoid patients (page 721, right column) and Lindy et al. obtained synovial tissue specimens from patients at the time of joint replacement surgery or diagnostic/therapeutic arthroscopy (page 1392, left column, third paragraph).

In summary, Claims 1-12 are all rejected as being obvious in view of the prior art, as discussed above.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. (See below.)

Pendas, et al. (1997) disclose the results to a structural analysis and promoter characterization of the human collagenase 3 gene (MMP13). The gene is clustered at chromosome 11q22 and a series of regulatory motifs were found.

Reboul et al. (1996) provide data that suggest the involvement of collagenase 3 in osteoarthritis cartilage pathophysiology.


Art Unit: 1651


Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Tue - Fri and alternate Mondays (8:00am - 4:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Lynda T Guo
Patent Examiner
December 20, 2002


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